



⁶ Applicant is to place a check mark here if English language Translation is attached.



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PTO/SB/08A (08-00)

Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Complete if Known			
		Application Number	10/089 367		
		Filing Date	March 28, 2002		
		First Named Inventor	RAPPUOLI		
		Group Art Unit	Unassigned- 1645		
Examiner Name	Unassigned				
Sheet	2	of	4	Attorney Docket Number	2302-1651 (PP01651.102)

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
SD	C1	ALMEIDA & ALPAR, "Nasal Delivery of Vaccines", <i>J. Drug Targeting</i> 3: 455-467.	
	C2	CAHILL et al., "Immune responses and protection against Bordetella pertussis infection after intranasal immunization of mice with filamentous haemagglutinin in solution or incorporated in biodegradable microparticles," <i>Vaccine</i> 13:455-462, 1995.	
	C3	CAHILL et al., "Mice are protected against Bordetella pertussis infection by intra-nasal immunization with filamentous haemagglutinin," <i>FEMS Microbiology Letters</i> 107: 211-216, 1993.	
	C4	Center for Disease Control and Prevention, "Pertussis Vaccination: Use of Acellular Pertussis Vaccines Among Infants AND young Children-recommendations of the Advisory Committee on Immunization Practices (ACIP)", <i>Morbid. Mortal. Weekly Rep.</i> 46 (RR-7): 1-25, 1997.	
	C5	DEL GIUDICE et al., "Molecular basis of vaccination," <i>Molecular Aspects of Medicine</i> 19: 1-70, 1998.	
	C7	DOUCE et al., "Mutants of Escherichia coli heat-labile toxin lacking ADP-ribosyltransferase activity act as nontoxic, mucosal adjuvants," <i>PNAS USA</i> 92: 1644-1648, 1995.	
	C8	FONTANA et al., "Construction of nontoxic derivatives of cholera toxin and characterization of the immunological response against the A subunit," <i>Infect. Immun.</i> 63: 2356-2360, 1995.	
	C9	GUSTAFSSON et al., "A controlled trial of a two-component acellular, a five-component acellular, and a whole-cell pertussis vaccine," <i>N. Engl. J. Med.</i> 334: 349-355, 1996.	
	C10	GUZMAN et al., "Antibody responses in the serum and respiratory tract of mice following oral vaccination with liposomes coated with filamentous hemagglutinin and pertussis toxoid," <i>Infect. Immun.</i> 61: 573-579, 1993.	

Examiner Signature		Date Considered	April 06
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		Group Art Unit	Unassigned 1645		
Examiner Name	Unassigned				
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S	C11	HAUSER et al., "Development and efficacy assessment of combination vaccines, with emphasis on acellular pertussis," <i>Dev. Biol. Stand.</i> 25: 251-255, 1998.	
	C12	JONES et al., "Orally administered microencapsulated Bordetella pertussis fimbriae protect mice from B. pertussis respiratory infection," <i>Infect. Immun.</i> 64: 489-494, 1996.	
	C13	MILLS et al., "A murine model in which protection correlates with pertussis vaccine efficacy in children reveals complementary roles for humoral and cell-mediated immunity in protection against Bordetella pertussis," <i>Infect. Immun.</i> 66: 94-602, 1998.	
	C14	PARK et al., "The mucosal adjuvanticity of two nontoxic mutants of Escherichia coli heat-labile enterotoxin varies with immunization routes." <i>Exp. Mol. Med.</i> 32: 72-78, 2000.	
	C15	PODDA et al., "Phase I clinical trial of an acellular pertussis vaccine composed of genetically detoxified pertussis toxin combined with FHA and 69 kDa," <i>Vaccine</i> 9: 741-745, 1991.	
	C16	RAPPUOLI et al., "Towards third-generation whooping cough vaccines," <i>Trends in biotechnology</i> 9: 232-238, 1991.	
	C17	RAPPUOLI, "Rational design of vaccines," <i>Nature Medicine</i> 3: 374-376, 1997.	
	C18	RYAN et al., "The adjuvant action of mutants of the heat labile toxin of E. coli for a nasally delivered acellular pertussis vaccine," <i>Immunology Letters</i> 69: 59, 1999.	
	C19	RYAN et al., "Mutants of Escherichia coli heat-labile toxin act as effective mucosal adjuvants for nasal delivery of an acellular pertussis vaccine: differential effects of the nontoxic AB complex and enzyme activity on Th1 and Th2 cells," <i>Infection and Immunity</i> 67: 6270-6280, 1999.	
	C20	SHAHIN et al., "Mucosal immunization with filamentous hemagglutinin protects against Bordetella pertussis respiratory infection," <i>Infect. Immun.</i> 60: 1482-1488, 1992.	
S	C21	SHAHIN et al., "Adjuvanticity and protective immunity elicited by Bordetella pertussis antigens encapsulated in poly(DL-lactide-co-glycolide) microspheres," <i>Infect. Immun.</i> 63: 1195-1200, 1995.	

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		Group Art Unit	Unassigned 1615		
Examiner Name	Unassigned				
Sheet	4	of	4	Attorney Docket Number	2302-1651 (PP01651.102)

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SD	C22	WALKER, "New strategies for using mucosal vaccination to achieve more effective immunization," <i>Vaccine</i> 12: 387-400, 1994.	
(Remaining rows are crossed out with a diagonal line)			

Examiner Signature	SD	Date Considered	Apr 7 06
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